

Notice of Allowability	Application No.	Applicant(s)	
	10/559,949	SILLEKENS ET AL.	
	Examiner	Art Unit	
	JOYCE TUNG	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 9/8/2011.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 2, 6, 12, 15-21, 23-33 (final claims 1-21).
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has **THREE MONTHS FROM THE "MAILING DATE"** of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>9/22/2011</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
|---|--|

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

EXAMINER'S AMENDMENT

The response filed 9/8/2011 to the Office action has been entered. Claims 2, 6, 12, 15-21, 23-31 are pending.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Alice M. Bonnen on 9/22/2011.

2. **The application has been amended as follows:**

Cancel claim 11.

Claim 12 (amended) A pair of oligonucleotides for amplification of a target sequence of the genome of SARS coronavirus, said pair selected from the group consisting of:

(a) a first oligonucleotide sequence of: SEQ ID NO:10: aattctaata cgactcacta tagggAACAT AACCAGTCGG TACAGCTACT A, and a second oligonucleotide sequence of: SEQ ID NO:7: GAAGCTATTC GTCACGTTTCG, or the complementary nucleotide sequence of SEQ ID NO:7;

(b) a first oligonucleotide sequence of SEQ ID NO:9: aattctaata cgactcacta tagggAAGAT GTTTAAACTG GTCACCTGGT GGA, and a second oligonucleotide sequence of SEQ ID NO:8: TCGGTGGATT GGCTTTGATG T, or the complementary nucleotide sequence of SEQ ID NO: 8;

(c) a first oligonucleotide sequence of SEQ ID NO:42: aattctaata cgactcacta tagggAAGGT GTGACTTCCA TGCCAA, and a second oligonucleotide sequence of SEQ ID NO:29: CAGAACAAAC CCAAGGAAAT T, or the complementary nucleotide sequence of SEQ ID NO:29; and any combination thereof.

Claim 32 (new) A test kit for the detection of SARS coronavirus in a sample, comprising:
the pair of oligonucleotides according to claim 12,
an oligonucleotide, for use as a probe, said probe comprising a molecular beacon probe
selected from the group consisting of:

SEQ ID NO:13: 5'- [6-FAM]-ccatgggCTGTCATGCAACTAGAGATGCTGTcccatgg-
[DabSyl]-3'; SEQ ID NO:45: 5'- [6-FAM]-cgcgatGTTCGTGCGTGGATTGGCTTatcgcg-
[DabCyl]-3'; and SEQ ID NO:30: 5'-[6-FAM]-ccatggACCAAGACCTAATCAGACAAccatgg-
[DabSyl]-3', and
suitable amplification reagents.

Claim 33 (new) The test kit according to claim 32, wherein the suitable amplification
reagents enable a NASBA transcription based amplification technique.

In claim 18, line 3, after "said probe comprising", delete --the oligonucleotide probe of
claim 15--, and insert --a molecular beacon probe selected from the group consisting of:

SEQ ID NO:13: 5'- [6-FAM]-ccatgggCTGTCATGCAACTAGAGATGCTGTcccatgg-
[DabSyl]-3'; SEQ ID NO:45: 5'- [6-FAM]-cgcgatGTTCGTGCGTGGATTGGCTTatcgcg-
[DabCyl]-3';and SEQ ID NO:30: 5'-[6-FAM]-ccatggACCAAGACCTAATCAGACAAccatgg-
[DabSyl]-3'--.

In claim 20, line 4, after "said probe comprising", delete --an oligonucleotide probe of
claim 15--, and insert --a molecular beacon probe selected from the group consisting of:

SEQ ID NO:13: 5'- [6-FAM]-ccatgggCTGTCATGCAACTAGAGATGCTGTcccatgg-
[DabSyl]-3'; SEQ ID NO:45: 5'- [6-FAM]-cgcgatGTTCGTGCGTGGATTGGCTTatcgcg-
[DabCyl]-3';and SEQ ID NO:30: 5'-[6-FAM]-ccatggACCAAGACCTAATCAGACAAccatgg-
[DabSyl]-3'--.

In claim 24, line 2, after "first oligonucleotide consists", delete --essentially--.

In claim 28, line 4, delete --claim 25-- and insert --SEQ ID NO:22: 5'-[6-FAM]-ccatgggCTACTACCGAAGAGCTACCCGACGAcccatgg- [DabSyl]-3'--.

In claim 30, line 5, delete --claim 25--, and insert --SEQ ID NO:22: 5'-[6-FAM]-ccatgggCTACTACCGAAGAGCTACCCGACGAcccatgg- [DabSyl]-3'--.

3. The following is an examiner's statement of reasons for allowance:

Concerning claims 2, and 15-21, no prior art has been found teaching or suggesting a pair of oligonucleotides selected from the group consisting of a pair of SEQ ID NOs: 4 and 7, 3 and 8, and 25 and 29, method of using such a pair of oligonucleotides for detecting SARS coronavirus nucleic acid in a sample, and 2 probe selected from the group consisting of SEQ ID NOs: 13, 45 and 30.

Concerning claims 12, and 32-33, no prior art has been found teaching or suggesting a pair of oligonucleotides selected from the group consisting of a pair of SEQ ID NOs: 10 and 7, 9 and 8, and, 42 and 29 or a kit containing such a pair of oligonucleotides.

Concerning claims 6, and 23-31, no prior art has been found teaching or suggesting a pair of primers for amplifying a target sequence of SARS coronavirus consisting essentially of a first oligonucleotide comprising at least 10 contiguous nucleotides of SEQ ID NO: 15 or the complement sequence of SEQ ID NO: 15, and a second oligonucleotide comprising at least 10 contiguous nucleotides of SEQ ID NO: 19 or the complement sequence of SEQ ID NO: 19.

The closest prior art is the reference of Laue et al. who disclose a method for detecting Severe Acute Respiratory Syndrome-associated virus (SARS) in which a real time RT-PCR reaction is performed by a forward primer and a reverse primer. Laue et al. do not disclose or suggest the instantly claimed primer pairs which have the properties discussed in the response filed 9/8/2011.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOYCE TUNG whose telephone number is (571)272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joyce Tung/
Examiner, Art Unit 1637
September 25, 2011

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637